



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0902]

Withdrawal of Approval of New Animal Drug Applications; Chorionic Gonadotropin; Naloxone; Oxymorphone; Oxytocin

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of four new animal drug applications (NADAs) at the sponsor's request because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: The sponsors in table 1 of this document have requested that FDA withdraw approval of the four NADAs listed because the products are no longer manufactured or marketed.

Table 1.--Withdrawal of Approval Requests

NADA No.	Trade Name (Drug)	Applicant
030-525	NUMORPHAN (oxymorphone hydrochloride) Injection	Endo Pharmaceuticals Inc., 100 Painters Dr., Chadds Ford, PA 19317
035-825	NARCAN (naloxone hydrochloride) Injection	Endo Pharmaceuticals Inc., 100 Painters Dr., Chadds Ford, PA 19317
046-822	VETOCIN (oxytocin) Injection	United Vaccines, A Harlan Sprague Dawley, Inc., Co., P.O. Box 4220 Madison, WI 53711
103-090	CHORTROPIN (chorionic gonadotropin) Injection	United Vaccines A Harlan Sprague Dawley, Inc., Co., P.O. Box 4220 Madison, WI 53711

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 Notice of withdrawal of approval of application (21 CFR 514.116), notice is given that approval of NADAs 030-525, 035-825, 046-822, and 103-090, and all supplements and amendments thereto, is hereby withdrawn, effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Elsewhere in this issue of the Federal Register, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: September 5, 2012.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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